

Serial No. 09/864,954

Filed: May 24, 2001

REMARKS

Claims 1 and 2 were pending in the subject application.

Claims 1 and 2 stand rejected by the Examiner.

Claims 1 and 2 are amended.

The specification is amended to correct an obvious typographical error. The claims are amended to more clearly define the subject matter of the present invention. No new matter added.

Applicants request reconsideration of the pending claims in light of the above claim amendments taken along with the following remarks.

Specification

The Examiner has objected to the specification because of an informality. Applicants thank the Examiner for her careful review of the specification. Specifically, the Examiner noted that the specification referred to Fig 5 at paragraph [0164]. Applicants have amended the specification to correct this typographical error. Reconsideration and withdrawal of the objection to the specification is respectfully requested.

Claim Rejections – 35 USC §112

The Examiner has rejected claims 1 and 2 under 35 USC 112, second paragraph, as being indefinite. More specifically, the Examiner rejects claims 1 and 2

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because it was unclear how the goal of the method set forth in the preamble is met by the process steps set forth in the method. Applicants have amended claims 1 and 2 to show the relationship between the hybridization, quantification and comparison steps in the determination of tumor progression potential. Therefore, Applicants respectfully that claims 1 and 2, with respect to this ground for rejection, is clear and definite as amended.

The Examiner further rejects claims 1 and 2 under 35 USC 112, second paragraph, for reciting a transitional phrase that was not clear. While not acquiescing to the merits of the Examiner's rejection, Applicants have adopted the Examiner's helpful suggestion to overcome this ground of rejection.

For the above reasons, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1 and 2 under 35 USC 112, second paragraph.

Claims 1 and 2 stand rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way to enable one skilled in the art to make and/or use the invention.

The Examiner urges, at page 6 of the office action, that "the over-expression of PKW in some breast cancer cell lines is not sufficient evidence to enable one skilled in the art to determine that this protein would necessarily be over-expressed in primary tumor tissue as compared to non-tumor tissue." (emphasis added) The Examiner further notes, at page 7 of the office action, that "[t]he teachings of the specification do not provide reliable guidance as to which cancers can be predicted using the claimed methods."

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Applicants submit that the method of the present invention is not trying to predict any specific type of cancer, but rather, is trying to show that expression of PKW in any cell may be indicative of a cell having tumor progression potential. The claims are specifically drawn to a process for determining whether or not a test sample has tumor progression potential. Support for this claim language can be found in the originally filed specification. For example, on page 9, paragraph [0133], it is stated that "in accordance with the present invention, the PKW nucleic acid is expressed in a greater amount in a tumor sample than in a sample free from tumor cells...." Further below in the same paragraph, it is stated that "a test sample having an upregulated PKW gene may have approximately 15 to 60 fold greater amount of PKW mRNA...."

The Multi Tissue Array disclosed in Figure 3 further supports this intention. This array clearly shows that PKW is not expressed elsewhere in the body in specific non-cancerous cells, except for salivary gland (see page 15, paragraph [0153]). The present invention is drawn to a method of showing that expression of PKW in any cell may be indicative of a cell having tumor progression potential.

For these reasons, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1 and 2 under 35 USC 112, first paragraph.

Conclusion

In summary, Applicants respectfully submit that the instant application is in condition for allowance. Early notice to that end is earnestly solicited.

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If a telephone conference would be of assistance in furthering prosecution of the subject application, applicants request that the undersigned be contacted at the number below.

No fee is required in connection with the filing of this Amendment. If any additional fees are deemed necessary, authorization is given to charge the amount of any such fee to Deposit Account No. 08-2525.

Respectfully submitted,



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